(4) *N-Isobutylpiperidone.* Proceed as directed in § 436.369 of this chapter.

(5) *Identity.* (i) Proceed as directed in § 436.211 of this chapter, using the sample preparation method described in paragraph (b)(1) of that section using a 1 to 2 percent mixture in potassium bromide.

(ii) The identity of rifabutin is confirmed by the qualitative comparison of the HPLC of the sample to the rifabutin working standard as directed in paragraph (b)(1) of this section.

[59 FR 40807, Aug. 10, 1994; 59 FR 46479, Sept. 8, 1994]

§ 455.90a Sterile vidarabine monohydrate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Vidarabine monohydrate is the monohydrate form of 9-β - D - arabinofuranosyl - 9H - purin - 6-amine. It is a white to off-white powder. It is so purified and dried that:

(i) Its vidarabine content is not less than 845 micrograms and not more than 985 micrograms of vidarabine per milligram.

(ii) It is sterile.

(iii) [Reserved]

(iv) Its loss on drying is not less than 5 percent and not more than 7 percent.

(v) Its specific rotation in dimethylformamide at 25° C is —60.5°±4.5°.

(vi) It passes the identity test for vidarabine.

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5(b) of this chapter, this drug shall be labeled ''vidarabine''.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for vidarabine content, sterility, loss on drying, specific rotation, and identity.

(ii) Samples required:

(*a*) For all tests except sterility: 10 packages, each containing approximately 500 milligrams.

(*b*) For sterility testing: 20 packages, each containing approximately 200 milligrams.

(b) *Tests and methods of assay*—(1) *Vidarabine content.* Proceed as directed in § 436.325 of this chapter.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(2) of that section, except use 100 milligrams in lieu of 300 milligrams.

(3) [Reserved]

(4) *Loss on drying.* Proceed as directed in § 436.200(e) of this chapter.

(5) *Specific rotation.* Using a solution containing 10 milligrams of vidarabine per milliliter in dimethylformamide and a polarimeter tube 1.0 decimeter in length, proceed as directed in § 436.210 of this chapter, except determine the specific rotation at 365 nanometers.

(6) *Identity.* Proceed as directed in § 436.211 of this chapter, using the 0.5 percent potassium bromide disc prepared as described in paragraph (b)(1) of that section.

[42 FR 44224, Sept. 2, 1977; 43 FR 9802, Mar. 10, 1978, as amended at 44 FR 30334, May 25, 1979; 50 FR 19921, May 13, 1985]

Subpart B—Oral Dosage Forms

§ 455.110 Chloramphenicol capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Chloramphenicol capsules are composed of chloramphenicol with or without one or more suitable and harmless diluents and lubricants. Each capsule contains 50, 100, or 250 milligrams of chloramphenicol. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of chloramphenicol that it is represented to contain. The chloramphenicol used conforms to the standards prescribed by § 455.10(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The chloramphenicol used in making the batch for potency, pH, specific rotation, melting range, absorptivity, and crystallinity.

(*b*) The batch for potency.

(ii) Samples required: